



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Nguyen *et al.*  
Serial No. : 10/677,977  
Filed : October 2, 2003

Art Unit : 1639  
Examiner : Wessendorf, Teresa D.  
Conf. No. : 9061  
Cust. No. : 77202

Title : **METHODS OF GENERATING AND SCREENING FOR PROTEASES  
WITH ALTERED SPECIFICITY**

**Mail Stop Petition**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PETITION FOR CORRECTION OF INFORMATION DISCLOSURE STATEMENT**  
**CLASSIFICATION UNDER 37 CFR 1.181**

Dear Sir:

Applicant respectfully submits this Petition under 37 CFR 1.181 to correct the misclassification of submitted Information Disclosure Statements.

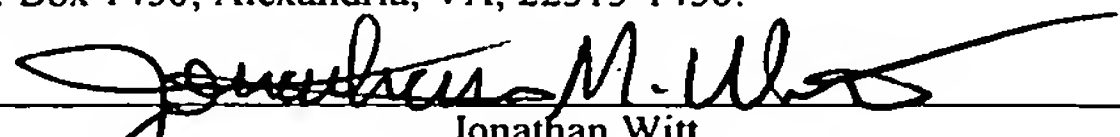
**Remarks** begin on page 2 of this paper.

**CERTIFICATE OF MAILING BY "EXPRESS MAIL"**

"Express Mail" Mailing Label EM 315355873 US

Date of Deposit: January 13, 2011

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Mail Stop Petition, Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

  
Jonathan Witt

## REMARKS

This Petition is submitted under 37 CFR 1.181 to request the correction of misclassified Information Disclosure Statements submitted in connection with the above-referenced application. Petitions submitted under 37 CFR 1.181 invoke the supervisory authority of the Director. Provided are this Petition under 37 CFR 1.181, an authorization to charge any fee due to Deposit Account No. 02-1818, and copies of eight (8) misclassified Information Disclosure Statements.

### Statement of Facts

Information Disclosure Statements were submitted in connection with the above-captioned application on November 16, 2007; August 7, 2008; September 12, 2008; June 11, 2009; July 10, 2009; October 1, 2009; March 31, 2010; and July 20, 2010. Each Information Disclosure Statement was prepared in accordance with 37 C.F.R 1.97 and 1.98. As required under 37 C.F.R 1.98, each Information Disclosure Statement contained 1) a list of all patents, publications, applications, or other information submitted for consideration by the Office, including a column that provides a space next to each document to be considered, for the Examiner's initials and a heading that clearly indicates that the list is an Information Disclosure Statement; and 2) legible copies of all items listed. The items either were in English or a translation was provided. Copies of the misclassified Information Disclosure Statements filed on November 16, 2007; August 7, 2008; September 12, 2008; June 11, 2009; July 10, 2009; October 1, 2009; March 31, 2010; and July 20, 2010 are attached.

The submitted Information Disclosure Statements included a tabular Form PTO-1449, which was classified as an "IDS," and a written disclosure of information. In each instance, the written disclosure of information was misclassified in PAIR as a "Transmittal Letter" (November 16, 2007, "Transmittal Letter" of 3 pages; August 7, 2008, "Transmittal Letter" of 4 pages; September 12, 2008, "Transmittal Letter" of 7 pages; June 11, 2009, "Transmittal Letter" of 3 pages; July 10, 2009, "Transmittal Letter" of 4 pages; October 1, 2009, "Transmittal Letter" of 5 pages; March 31, 2010, "Transmittal Letter" of 3 pages; and July 20, 2010, "Transmittal Letter" of 2 pages). Consequently the information contained therein was not considered or reviewed by the Examiner. The written disclosure often contains information including the identification of English language translations of items listed on the Form PTO-1449, information regarding joint ownership and copending applications, and other information that is not amenable to a tabular

Applicant : Nguyen *et al.*  
Serial No. : 10/677,977  
Filed : October 2, 2003

Attorney's Docket No.: 3800003.00007 / 4905  
Petition for Correction of Information Disclosure Statement Classification

format. Information Disclosure Statements not only provide documents, but also can include discussions material to such documents and descriptions of other relevant information.

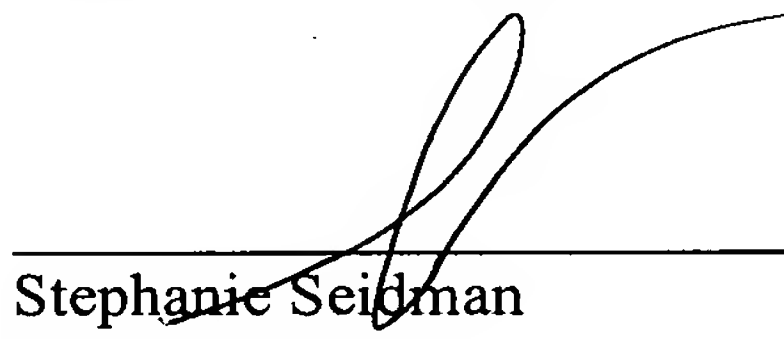
Accordingly, this Petition has been filed to request the reclassification of the Information Disclosure Statements. The Information Disclosure Statements submitted on November 16, 2007; August 7, 2008; September 12, 2008; June 11, 2009; July 10, 2009; October 1, 2009; March 31, 2010; and July 20, 2010 were filed in accordance with 37 C.F.R. 1.97-1.98 and should therefore be classified as Information Disclosure Statements.

### **Conclusion**

Accordingly, correction of the classification in PAIR of the Information Disclosure Statements submitted on November 16, 2007; August 7, 2008; September 12, 2008; June 11, 2009; July 10, 2009; October 1, 2009; March 31, 2010; and July 20, 2010 in connection with the above-referenced application and consideration by the Examiner of the documents and information contained therein, respectfully is requested.

☒ The Commissioner is hereby authorized to charge the fee for the petition any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 02-1818.

Respectfully submitted,



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Stephanie Seidman  
Reg. No. 33,779

Attorney Docket No. 3800003.00007 / 4905  
**Address all correspondence to: 77202**  
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K&L Gates LLP  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nguyen et al.                      Art Unit : 1639  
Serial No. : 10/677,977                      Examiner : Teresa D. Wessendorf  
Filed : October 2, 2003                      Conf. No. : 9061  
Cust No. : 20985  
Title : METHODS OF GENERATING AND SCREENING FOR PROTEASES  
WITH ALTERED SPECIFICITY

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, a check for the filing fee of \$180.00 is enclosed. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (2 pages) and copies of the cited non U.S. Patent documents are provided herewith.

11/20/2007 CNEGAL 00000003 10677977  
01 FC:1006 180.00 OP

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
"Express Mail" Mailing Label Number EV 740123660 US  
Date of Deposit November 16, 2007  
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

Stephanie Seidman

Applicant : Nguyen et al.  
Serial No. : 10/677,977  
Filed : October 2, 2003

Attorney's Docket No.: 19049-005001/4905  
Supplemental Information Disclosure Statement

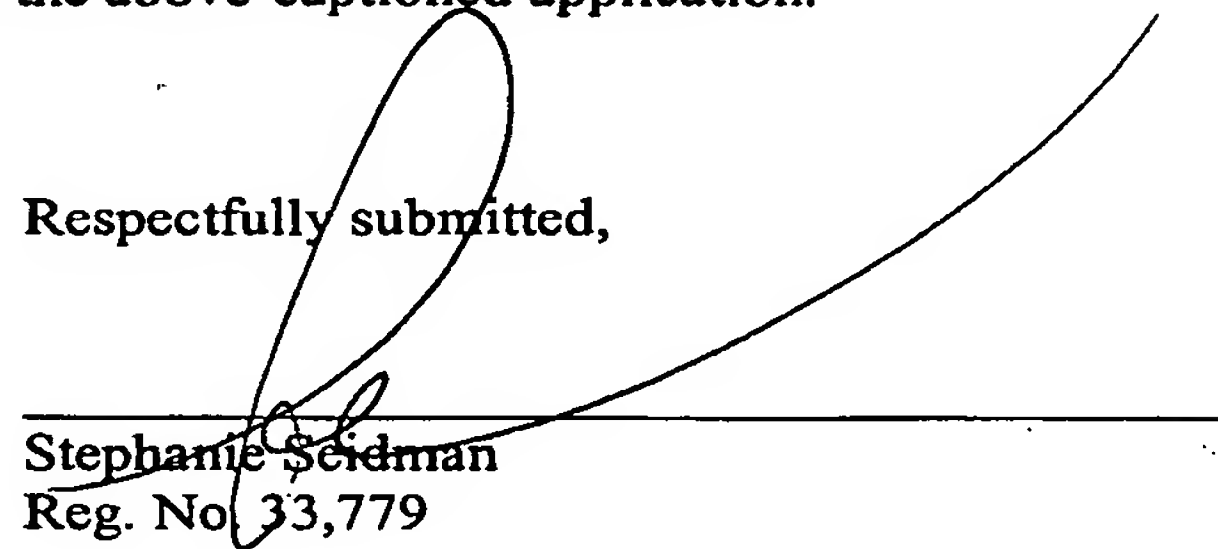
The documents cited on the Forms PTO-1449 are in the English language, with the exception of item noted below. Item AJ (Fautrel, B. *et al. Rev Med Interne* 21(10):872-888 (2000)) is in the French language and is supplied with an English language summary on the first page of the article. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

The above-captioned application designates four inventors, Jack Nguyen, Chris Thanos, Charles Craik, and Sandra Waugh Ruggles, and two assignees, Catalyst Biosciences and Regents of the University of California. Jack Nguyen and Chris Thanos assigned to Catalyst Biosciences. Charles Craik and Sandra Waugh Ruggles assigned to Regents of the University of California. Thus, the above-captioned application has joint inventors and two assignees.

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the information, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

  
Stephanie Seidman  
Reg. No. 33,779

Attorney Docket No. 19049-005001/4905  
Address all correspondence to:  
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email: seidman@fr.com





<b>Substitute Form PTO-1449</b> (Modified)  <b>List of Patents and Publications for Applicant's Information Disclosure Statement</b>  (37 CFR §1.98(b))	<b>U.S. Department of Commerce</b> <b>Patent and Trademark Office</b>	<b>Attorney's Docket No.</b> 19049-005001/4905	<b>Application No.</b> 10/677,977
	<b>Applicant</b> Nguyen et al.		
	<b>Filing Date</b> October 2, 2003	<b>Group Art Unit</b> 1639	

**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	6,383,775	05/07/02	Duff et al.	435	70.100	03/11/99

**Foreign Patent Documents or Published Foreign Patent Applications**

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AB	WO 99/11801	03/11/99	WIPO				
	AC	WO 00/78332	12/28/00	WIPO				
	AD	WO 01/42432	06/14/01	WIPO				
	AE	WO 02/090300	11/14/02	WIPO				

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	AF	Aggarwal, B. et al., "Human tumor necrosis factor production, purification, and characterization," <i>Journal of Biological Chemistry</i> , 260(4):2345-2354, (1985).
	AG	Altamirano, M.M., et al., "Directed evolution of new catalytic activity using the alpha/beta-barrel scaffold," <i>Nature</i> , 403(6770):617-622, (2000).
	AH	Ausubel, et al. Eds., "Protein Expression," In: <i>Current Protocols in Molecular Biology</i> , John Wiley & Sons, Inc. New York, N.Y., pp 16.0.1 – 16.0.4. (1987).
	AI	Empie, M.W., and M. Laskowski, "Thermodynamics and kinetics of single residue replacements in avian ovomucoid third domains: effect on inhibitor interactions with serine proteinases," <i>Biochemistry</i> , 21(10):2274-2284, (1982).
	AJ	Fautrel, B., et al., "Interest of anti-TNF- $\alpha$ treatment in inflammatory and infectious diseases," <i>Rev Med Interne</i> , 21(10):872-888, (2000). [Article in the French language and English summary on 1st page of article.]
	AK	Forlani, F., et al., "Evidence that elongation of the catalytic loop of the <i>Azotobacter vinelandii</i> rhodanese changed selectivity from sulfur- to phosphate-containing substrates," <i>Protein Engineering</i> , 16(7):515-519, (2003).
	AL	Gayle, R.B., et al., "Identification of regions in interleukin-1 alpha important for activity," <i>Journal of Biological Chemistry</i> , 268(29):22105-22111, (1993).
	AM	Klinkenberg, M., et al., "A dominant negative mutation in <i>Saccharomyces cerevisiae</i> methionine aminopeptidase-1 affects catalysis and interferes with the function of methionine aminopeptidase-2," <i>Archives of Biochemistry and Biophysics</i> , 347(2):193-200, (1997).
	AN	Koehl, et al., "De novo protein design. I. In search of stability and specificity," <i>Journal of Molecular Biology</i> , 293(5):1161-1181, (1999).
	AO	Koltermann, A. et al., "Principles and methods of evolutionary biotechnology," <i>Biophysical Chemistry</i> , 66(2-3):159-177, (1997).

<b>Examiner Signature</b>	<b>Date Considered</b>
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 19049-005001/4905		Application No. 10/677,977	
<b>List of Patents and Publications for Applicant's Information Disclosure Statement</b>  (37 CFR §1.98(b))				Applicant Nguyen et al.			
				Filing Date October 2, 2003		Group Art Unit 1639	
<b>Other Documents (include Author, Title, Date, and Place of Publication)</b>							
Examiner Initial	Desig. ID	Document					
	AP	Ruggles, S., et al., "Characterization of structural determinants of granzyme B reveals potent mediators of extended substrate specificity," Journal of Biological Chemistry, 279(29):30751-30759, (2004).					
	AQ	Smith, T., et al., "Direct selection for sequences encoding proteases of known specificity," Proceedings of the National Academy of Sciences of the United States of America, 88:5159-5162, (1991).					
	AR	Whisstock, J.C. and A.M. Lesk, "Prediction of protein function from protein sequence and structure," Q Review Biophys., 36(3):307-340, (2003).					
	AS	Zhou, J.M., et al., "Kinetics of trypsin inhibition by its specific inhibitors," Biochemistry, 28(3):1070-1076, (1989).					

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nguyen et al.                      Art Unit : 1639  
Serial No. : 10/677,977                      Examiner : Teresa D. Wessendorf  
Filed : October 2, 2003                      Conf. No. : 9061  
Cust. No. : 77202  
Title : METHODS OF GENERATING AND SCREENING FOR PROTEASES  
WITH ALTERED SPECIFICITY

**Mail Stop RCE**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§1.97-1.98**

Dear Sir:

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 02-1818.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (1 page) and copies of the cited non U.S. patent documents are provided herewith.

The documents cited on the Forms PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following pending U.S. and International Applications having one or more common inventors and/or common ownership:

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
"Express Mail" Mailing Label Number EM 247735535 US  
Date of Deposit August 7, 2008.  
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Kethya Teuk



Applicant : Nguyen et al.  
Serial No. : 10/677,977  
Filed : October 2, 2003

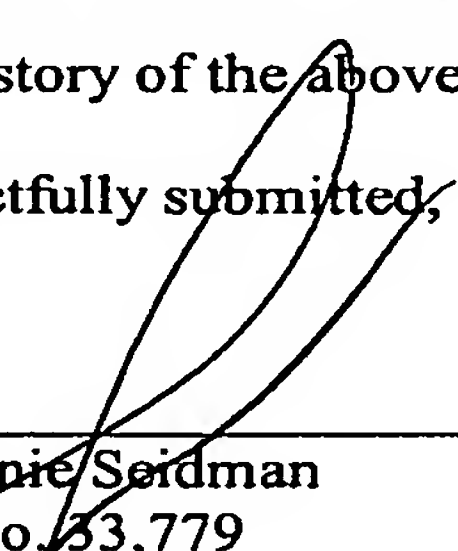
Attorney's Docket No.: 119357-00007 / 4905  
Supplemental Information Disclosure Statement

U.S.S.N.	Filing Date	Publ. No.	Publ. Date	Docket No.
12/005,949	12/28/07	n/a	n/a	4905B
12/005,953	12/28/07	n/a	n/a	4912B
12/082,662	04/11/08	n/a	n/a	4913
Int'l App. No.	Filing Date	Publ. No.	Publ. Date	Docket No.
PCT/US07/015571	07/05/07	WO 08/045148	04/17/08	4902PC
PCT/US08/004795	04/11/08	n/a	n/a	4913PC

Although these documents and applications are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

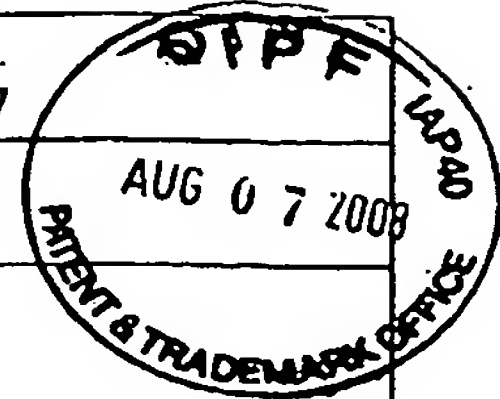
Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

  
Stephanie Seidman  
Reg. No. 33,779

Attorney Docket No. 119357-00007 / 4905  
Address all correspondence to:  
Stephanie Seidman  
Bell, Boyd & Lloyd, LLP  
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San Diego, California 92130  
Telephone: (858) 509-7410  
Facsimile: (858) 509-7460  
email: sseidman@bellboyd.com

Substitute Form PTO-1449 (Modified)  <b>List of Patents and Publications for Applicant's Information Disclosure Statement</b>  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 119357-007/4905	Application No. 10/677,977
	Applicant Nguyen et al.			
	Filing Date October 2, 2003		Group Art Unit 1639	



U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2006/269538	11/30/06	Koltermann et al.	424	94.63	05/26/06
	AB	2008/0160558	07/03/08	Koltermann et al.	435	23	05/09/07

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AC	1726643	11/29/06	EP				
	AD	WO 06/125827	11/30/06	WIPO				

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AF	Lasters et al., "Enzymatic properties of phage-displayed fragments of human plasminogen," European J Biochemistry, 244:946-952, (1997).
	AG	Lien et al., "Combinatorial strategies for the discovery of novel protease specificities," Combi Chem High Throughput Screening, 2:73-90, (1999).
	AH	Soumillion et al., "Phage display of enzymes and in vitro selection for catalytic activity," App Biochem and Biotechnology 47:175-189, (1994).

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nguyen et al.                      Art Unit : 1639  
Serial No. : 10/677,977                      Examiner : Teresa D. Wessendorf  
Filed : October 2, 2003                      Conf. No. : 9061  
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WITH ALTERED SPECIFICITY

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§1.97-1.98**

Dear Sir:

This Supplemental Information Disclosure Statement is filed pursuant to 37 C.F.R. §1.97(d) and includes a statement in accordance with 37 C.F.R. §1.97(e) and 1.704(d). The statement applies to an Israeli Official Action and information cited therein, listed on Form PTO-1449 (1 page) provided herewith. Because this Supplemental Information Disclosure Statement is filed after the receipt of a Non-Final Office Action on the Merits for the above-captioned application and is accompanied by a Statement pursuant to 37 C.F.R. § 1.97(e) and 1.704(d), no fee should be due. However, if it is determined that a fee is due, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 02-1818.

As noted in the attached statement, the information provided herewith was first cited in a communication from a foreign patent office, in a counterpart foreign application, not more than three months prior to the filing of this statement. Neither this information nor the communication was received by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this Supplemental Information Disclosure Statement.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
"Express Mail" Mailing Label Number EM 247738324 US  
Date of Deposit: September 12, 2008.  
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Ketya Teuk

provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (1 page) and copies of the cited non U.S. patent documents are provided herewith.

The documents cited on the Forms PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

A Copy of an Official Action (Document I), issued August 19, 2008, in connection with corresponding Israeli Patent Application No. 167744 is provided. This Israeli patent application is a National Stage Entry of International Patent Application No. PCT/US US2003/031733, which claims priority to U.S. Provisional Application Serial No. 60/415,388, to which the instant application claims priority. The table below lists Document I and includes a column that provides a space next to the documents to be considered, for the Examiner's initials.

Examiner Initial	Document No.	Document
	I	Copy of Official Action, issued August 19, 2008, in connection with Israeli Patent Application No. 167744

In the Official Action, issued August 19, 2008, the following documents are cited: 1) US 6,271,012; 2) Guinto et al., "Unexpected crucial role of residue 225 in serine proteases" Proc Natl Acad Sci U S A. 96:1852-1857 (1999); 3) Hegyi et al., "Mutational analysis of the active centre of coronavirus 3C-like proteases" J. Gen. Virology 83:581-593 (2002); 4) Heinis et al. "Selection of catalytically active biotin ligase and trypsin mutants by phage display" Prot. Eng. 14:1043-1052 (2001); 5) Takagi et al. "Construction of novel subtilisin E with high specificity, activity and productivity through multiple amino acid substitutions" Prot. Eng. 10:985-989 (1997); and 6) US 6,383,775. Documents 1-5 are made of record in the instant application in this Information Disclosure Statement, supplied with Forms PTO-1449 and copies of the cited non U.S. patent documents. Document 6 is made of record in the instant application in an Information Disclosure Statement, supplied with Forms PTO-1449 and copies of the cited non U.S. patent documents, filed November 16, 2007.

Although these documents and applications are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the

Applicant : Nguyen et al.  
Serial No. : 10/677,977  
Filed : October 2, 2003

Attorney's Docket No.: 119357-00007 / 4905  
Supplemental Information Disclosure Statement

documents, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

---

Stephanie Seidman  
Reg. No. 33,779

Attorney Docket No. 119357-00007 / 4905  
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Facsimile: (858) 509-7460  
email: sseidman@bellboyd.com



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nguyen et al.                      Art Unit : 1639  
Serial No. : 10/677,977                      Examiner : Teresa D. Wessendorf  
Filed : October 2, 2003                      Conf. No. : 9061  
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Title : METHODS OF GENERATING AND SCREENING FOR PROTEASES  
WITH ALTERED SPECIFICITY

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FOR SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT IN ACCORDANCE WITH 37 C.F.R. § 1.97(e) AND 1.704(d)**

Dear Sir:

1. This statement is being made for the Supplemental Information Disclosure Statement accompanying this certification.

2. I, Stephanie Seidman, hereby state that each item of information contained in the Supplemental Information Disclosure Statement provided herewith was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. Further, neither the information nor the communication was received by any individual designated in C.F.R. § 1.56(c) in the instant application more than thirty days prior to the filing of the Supplemental Information Disclosure Statement provided herewith. The provided information was first cited in a communication from the Israeli Patent Office, dated August 19, 2008, in connection with Israel Patent Application No. 167744. This Israeli patent application is a National Stage entry of International Patent Application No. PCT/US03/031719, which claims priority to U.S. Provisional Application Serial No. 60/415,388, to which the instant application likewise claims priority.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
"Express Mail" Mailing Label Number EM 247738324 US  
Date of Deposit. September 12, 2008.  
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR § 1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Kethya Teuk

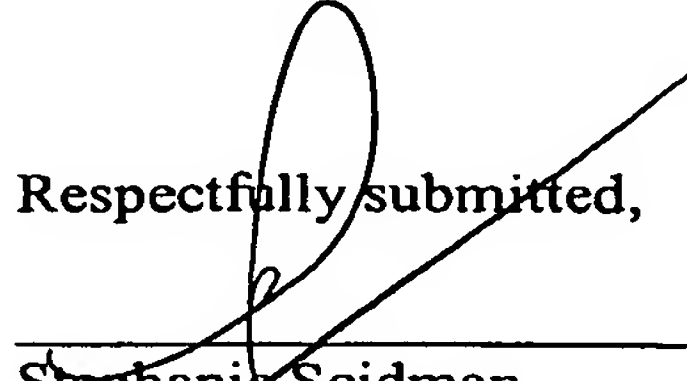


Applicant : Nguyen et al.  
Serial No. : 10/677,977  
Filed : October 2, 2003

Attorney's Docket No.: 0119357-00007/4905  
Statement in accordance with 37 C.F.R. § 1.97(e) and 1.704(d)

3. The person making this statement is a registered practitioner and signs below on the basis of information in the attorney's file.

Respectfully submitted,

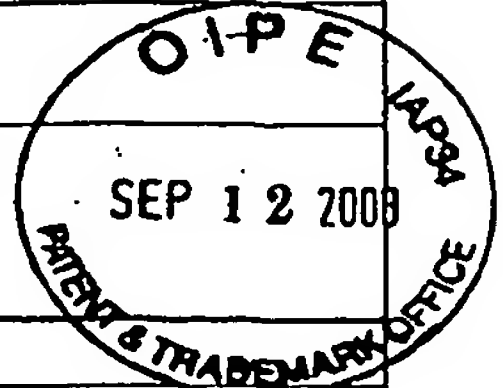


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Stephanie Seidman  
Reg. No. 58,906

Attorney Docket No. 0119357-00007/4905  
**Address all correspondence to: 77202**  
Stephanie Seidman  
BELL, BOYD & LLOYD LLP  
3580 Carmel Mountain Road, Suite 200  
San Diego, CA, 92130  
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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 119357-00007/4905	Application No. 10/677,977
List of Patents and Publications for Applicant's Information Disclosure Statement  (37 CFR §1.98(b))		Applicant Nguyen et al.	
		Filing Date October 2, 2003	Group Art Unit 1639



U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	6,271,012	08/07/01	Van Eekelen	435	221	06/29/94

Foreign Patent Documents or Published Foreign Patent Applications							
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes No
None.							

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AB	Guinto et al., "Unexpected crucial role of residue 225 in serine proteases," Proc Natl Acad Sci U S A. 96:1852-1857 (1999).
	AC	Hegyi et al., "Mutational analysis of the active centre of coronavirus 3C-like proteases." J. Gen. Virology 83:581-593 (2002).
	AD	Heinis et al., "Selection of catalytically active biotin ligase and trypsin mutants by phage display." Prot. Eng. 14:1043-1052 (2001).
	AE	Takagi et al., "Construction of novel subtilisin E with high specificity, activity and productivity through multiple amino acid substitutions" Prot. Eng. 10:985-989 (1997).

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nguyen et al.                      Art Unit : 1639  
Serial No. : 10/677,977                      Examiner : Teresa D. Wessendorf  
Filed : October 2, 2003                      Conf. No. : 9061  
Cust. No. : 77202  
Title : METHODS OF GENERATING AND SCREENING FOR PROTEASES  
WITH ALTERED SPECIFICITY

**Mail Stop RCE**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN**  
**ACCORDANCE WITH 37 C.F.R. §§1.97-1.98**

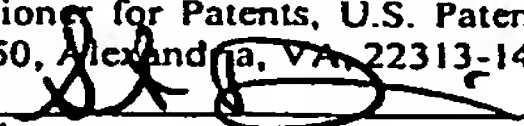
Dear Sir:

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 02-1818.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (2 pages) and copies of the cited non U.S. patent documents are provided herewith.

The documents cited on the Forms PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Copies of Examination Reports (Documents 1 and 2), issued June 25, 2008 and April 15, 2009, in connection with corresponding Australian Patent Application No. 2003282724, are provided. Copies of Examination Reports (Documents 3 and 4), issued August 8, 2008

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
"Express Mail" Mailing Label Number EM 315454292 US.  
Date of Deposit June 11, 2009.  
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.  
  
Steven Dennis

and February 24, 2009, in connection with corresponding New Zealand patent Application No. 539242, are provided. A copy of an Office Action (Document 5), issued February 24, 2009, in connection with U.S. Application Serial No. 11/104,111, is provided. A copy of a Search Report and Written Opinion (Document 6), issued March 4, 2009, in connection with Singapore Patent Application No. 200704897-8, is provided. A copy of a Supplementary European Search Report (Document 7), issued May 14, 2009, in connection with European Patent Application No. 03774608.8, is provided. The table below lists Documents 1-7 and includes a column that provides a space next to the documents to be considered, for the Examiner's initials.

Examiner Initial	Document No.	Document
	1	Examination Report, issued June 25, 2008, in connection with Australian Patent Application No. 2003282724
	2	Examination Report, issued April 15, 2009, in connection with Australian Patent Application No. 2003282724
	3	Examination Report, issued August 8, 2008, in connection with New Zealand Patent Application No. 539242
	4	Examination Report, issued February 24, 2009, in connection with New Zealand Patent Application No. 539242
	5	Office Action, issued February 24, 2009, in connection with U.S. Application Serial No. 11/104,111
	6	Search Report and Written Opinion, issued March 4, 2009, in connection with Singapore Patent Application No. 200704897-8
	7	Supplementary European Search Report, issued May 14, 2009, in connection with European Patent Application No. 03774608.8

In the Office Action dated, December 11, 2008, the Examiner indicated that the Information Disclosure Statement (IDS) submitted on September 12, 2008 was considered and initialed by the Examiner. The IDS filed on September 12, 2008 contained a Table listing an Office Action issued in a corresponding Israeli Patent Application. This table was not initialed by the Examiner. This IDS included the application number of the application in which the IDS was being submitted, a column that provides a blank space next to each citation for the Examiner's initials, a heading on the listing that clearly indicates the list is an Information Disclosure Statement, and copies of listed documents. Therefore, the September 12, 2008 IDS is in compliance with 37 CFR §§ 1.97, 1.98 and MPEP § 609 and Applicant

Applicant : Nguyen et al.  
Serial No. : 10/677,977  
Filed : October 2, 2003

Attorney's Docket No.: 119357-00007 / 4905  
Supplemental Information Disclosure Statement

respectfully requests that Examiner consider and initial all information listed in the tables submitted in the IDS filed September 12, 2008.

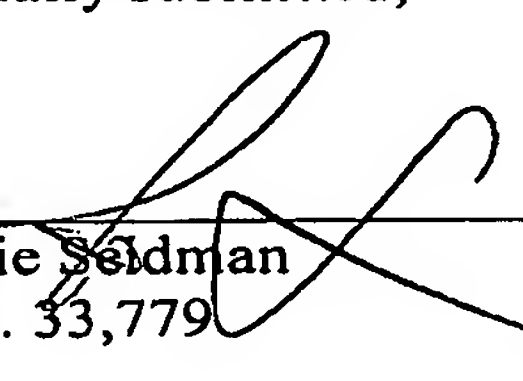
Applicant also makes known to the Examiner the following pending U.S. and International Applications having one or more common inventors and/or common ownership:

U.S.S.N.	Filing Date	Publ. No.	Publ. Date	Docket No.
11/825,627	07/05/07	2009-0123452	05/14/09	4902
12/005,949	12/28/07	2009-0136477	05/28/09	4905B
12/005,953	12/28/07	2009-0047210	02/19/09	4912B

Although these documents and applications are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

  
\_\_\_\_\_  
Stephanie Seidman  
Reg. No. 33,779

Attorney Docket No. 119357-00007 / 4905  
Address all correspondence to: 77202  
Stephanie Seidman  
K&L Gates LLP  
3580 Carmel Mountain Road, Suite 200  
San Diego, California 92130  
Telephone: (858) 509-7410  
Facsimile: (858) 509-7460  
email: stephanie.seidman@klgates.com



Substitute Form PTO-1449 (Modified)  <b>List of Patents and Publications for Applicant's Information Disclosure Statement</b>  (37 CFR §1.98(b))	U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 0119357-00007/4905	Application No. 10/677,971
	Applicant Nguyen et al.			
	Filing Date October 2, 2003		Group A Unit 1639	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2006/0002916	01/05/06	Ruggles et al.	424	94.63	01/05/06
	AB	2006/0024289	02/02/06	Ruggles et al.	424	94.64	04/12/05
	AC	2006/0099625	05/11/06	Craik et al.	435	6	10/18/05
	AD	2006/0104979	05/18/06	Craik et al.	424	146.1	10/18/05
	AE	2007/0093443	04/26/07	Madison et al.	514	44	10/20/06
	AF	2008/0051559	02/28/08	Craik et al.	530	350	01/31/07
	AG	2009/0047210	02/19/09	Ruggles et al.	424	1.11	12/28/07
	AH	2009/0098103	04/16/09	Madison et al.	434	94.64	04/11/08
	AI	2009/0123452	05/14/09	Madison	424	94.64	07/05/07
	AJ	2009/0136477	05/28/09	Nguyen	424	94.64	12/28/07
	AK	5,486,602	01/23/96	Sambrook et al.	536	23.2	12/17/93
	AL	7,030,231	04/18/06	Craik et al.	536	23.1	09/30/99
	AM	7,227,009	06/05/07	Craik et al.	536	23.1	10/18/05
	AN	7,335,504	02/26/08	Haupts et al.	435	226	06/18/04

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
None.								

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AO	Amerik et al., "Identification, sequence analysis, and characterization of cDNA clones encoding two granzyme-like serine proteinases from rat duodenum," FEBS Letters 324(2):226-230 (1993).
	AP	Cantwell et al., "Rational design of a potent anticoagulant thrombin," J. Biol. Chem. 275(51):39827-39830 (2000).
	AQ	Caputo et al., "Conversion of the substrate specificity of mouse proteinase granzyme B," Nature Structural Biology 1(6):364-367 (1994).
	AR	Cascola-Rosen et al., "Cleavage by granzyme B is strongly predictive of autoantigen status: Implications for initiation of autoimmunity," J. Exp. Med. 190(6):815-825 (1999).
	AS	Nelsestuen et al., "Elevated function of blood clotting factor VIIa mutants that have enhanced affinity for membranes," J Biol Chem 276(43):39825-39831 (2001).
	AT	Oberst et al., "The activation of matriptase requires its noncatalytic domains, serine protease domain, and its cognate inhibitor," J Biol Chem 278(29):26773-26779 (2003).
	AU	Ogata et al. "Comparison of thrombolytic therapies with mutant tPA (lanoteplase/SUN9216) and recombinant tPA (alteplase) for acute myocardial infarction," Japanese Circulation Journal 62(11):801-806 (1998).

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 0119357-00007/4905	Application No. 10/677,977
List of Patents and Publications for Applicant's Information Disclosure Statement  (37 CFR §1.98(b))				Applicant Nguyen et al.	
				Filing Date October 2, 2003	
	AV	Rotonda et al., "The three-dimensional structure of human granzyme B compared to caspase-3, key mediators of cell death with cleavage specificity for aspartic acid in PI.," Chemistry & Biology 8(4):357-368 (2001).			
	AW	Trapani, J., "Granzymes: a family of lymphocyte granule serine proteases," Genome Biology 2(12):3014.1-3014.7 (2001).			
	AX	Tsiang et al., "Protein engineering thrombin for optimal specificity and potency of anticoagulant activity in vivo," Biochemistry 35:16449-16457 (1996).			
	AY	Venekei et al., "A rapid and effective procedure for screening protease mutants," Protein Engineering 9(1):85-93 (1996).			

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nguyen et al.  
Serial No. : 10/677,977  
Filed : October 2, 2003  
Cust. No. : 77202  
Title : METHODS OF GENERATING AND SCREENING FOR PROTEASES  
WITH ALTERED SPECIFICITY

Art Unit : 1639  
Examiner : Teresa D. Wessendorf  
Conf. No. : 9061

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§1.97-1.98**

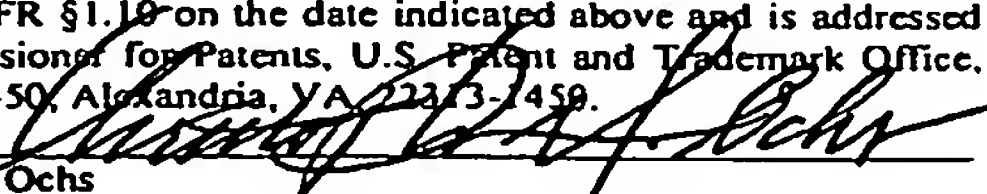
Dear Sir:

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 02-1818.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (1 page) and copies of the cited non U.S. patent documents are provided herewith.

The documents cited on the Forms PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

A copy of an Examiner's Report (Document 1), issued June 16, 2009, in connection with Japanese Patent Application No. 2004-541703, is provided. The table below lists Documents 1 and includes a column that provides a space next to the documents to be considered, for the Examiner's initials.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
"Express Mail" Mailing Label Number EM 315454765 US.  
Date of Deposit: July 10, 2009.  
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.  
  
Christopher Ochs

Applicant : Nguyen et al.  
Serial No. : 10/677,977  
Filed : October 2, 2003

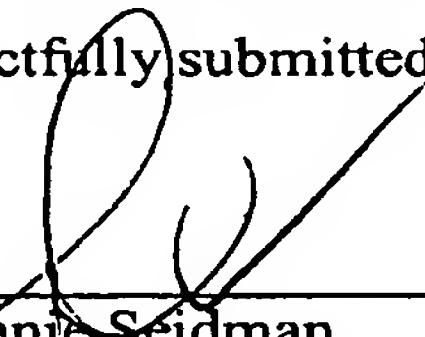
Attorney's Docket No.: 0119357-00007 / 4905  
Supplemental Information Disclosure Statement

Examiner Initial	Document No.	Document
	1	Examiner's Report, issued June 16, 2009, in connection with Japanese Patent Application No. 2004-541703

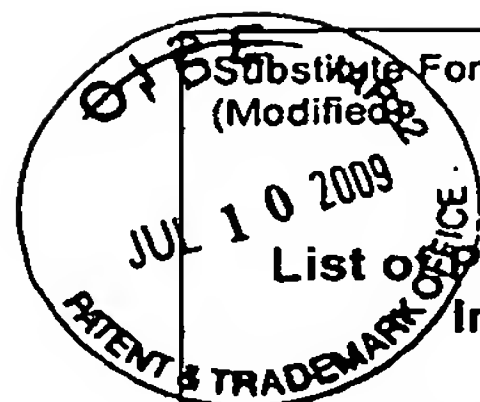
Although these documents and applications are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

  
\_\_\_\_\_  
Stephanie Seidman  
Reg. No. 33,779

Attorney Docket No. 0119357-00007 / 4905  
**Address all correspondence to: 77202**  
Stephanie Seidman  
K&L Gates LLP  
3580 Carmel Mountain Road, Suite 200  
San Diego, California 92130  
Telephone: (858) 509-7410  
Facsimile: (858) 509-7460  
email: stephanie.seidman@klgates.com


 Substitute Form PTO-1449  
 (Modified)

 U.S. Department of Commerce  
 Patent and Trademark Office

 Attorney's Docket No.  
 0119357-00007/4905

 Application No.  
 10/677,977

**List of Patents and Publications for Applicant's  
 Information Disclosure Statement**

(37 CFR §1.98(b))

 Applicant  
 Nguyen et al.

 Filing Date  
 October 2, 2003

 Group Art Unit  
 1639

**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
None.							

**Foreign Patent Documents or Published Foreign Patent Applications**

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
None.								

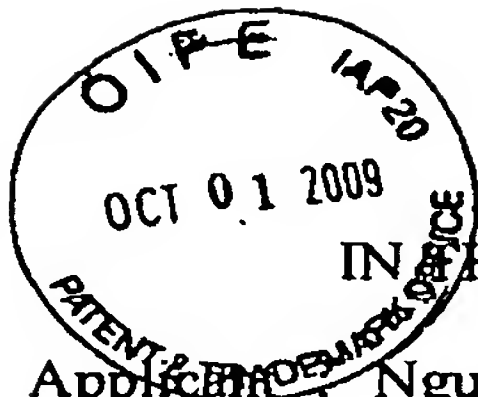
**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	AA	Dang et al., "Rational engineering of activity and specificity in a serine protease," Nature Biotechnology, 15(2):146-149 (1997).
	AB	Jallat et al., "Altered specificities of genetically engineered alpha1 antitrypsin variants," Protein Engineering 1(1):29-35 (1986).

Examiner Signature

Date Considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Nguyen *et al.*

Serial No. : 10/677,977

Filed : October 2, 2003

Cust. No. : 77202

Title : METHODS OF GENERATING AND SCREENING FOR PROTEASES  
WITH ALTERED SPECIFICITY

Art Unit : 1639

Examiner : Teresa D. Wessendorf

Conf. No. : 9061

**Mail Stop Amendment**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§1.97-1.98**

Dear Sir:

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 02-1818.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98.

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A Copy of an Examination Report (Document 1), issued June 24, 2009, in connection with New Zealand Patent Application No. 577815, is provided. A Copy of an Examination Report (Document 2), issued September 4, 2009, in connection with Australian Patent Application No. 2003282724, is provided. A Copy of an Examination Report (Document 3), issued September 3, 2009, in connection with European Patent Application No. 03774608.8, is provided. The table below lists Documents 1-3 and includes a column that provides a space next to the documents to be considered, for the Examiner's initials.

**CERTIFICATE OF MAILING BY "EXPRESS MAIL"**

"Express Mail" Mailing Label Number EM 315451659 US

Date of Deposit: October 1, 2009

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Christopher M. Ochs

Examiner Initial	Document No.	Document
	1	Examination Report, issued June 24, 2009, in connection with New Zealand Patent Application No. 577815
	2	Examination Report, issued September 4, 2009, in connection with Australian Patent Application No. 2003282724
	3	Examination Report, issued September 3, 2009, in connection with European Patent Application No. 03774608.8

The Examiner is requested to please review the file history of this application in PAIR. When submitting Information Disclosure Statements, the undersigned includes a transmittal letter, a paper providing information, and a Form PTO-1449. In some instances, the paper providing information includes a table with documents that require initials by the Examiner. It has just come to the attention of the undersigned that Information Disclosure Statements have been misclassified in PAIR. Also the documents have been separated such that, at best, only parts of the documents are getting to the Examiner for review. In the Supplemental Information Disclosure Statements, filed on September 12, 2008, June 11, 2009, and July 10, 2009, the transmittal letter and accompanying IDS letter providing information have been classified together as transmittal letter (TRAN.LET). To address this, the undersigned is contacting the Examiner to discuss and identify documents that have not been considered.

Although these documents and applications are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

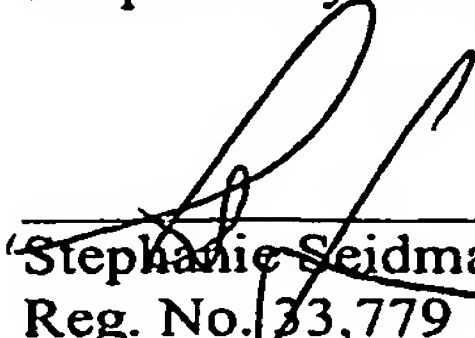


Applicant : Nguyen et al.  
Serial No. : 10/677,977  
Filed : October 2, 2003

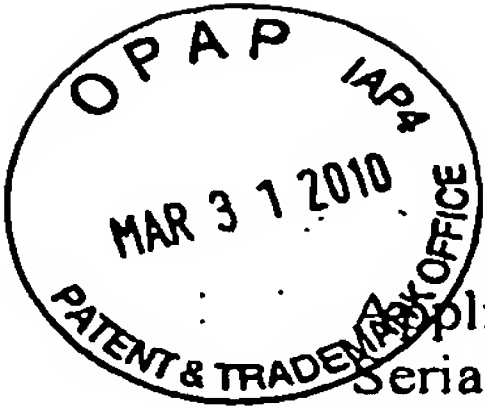
Attorney Docket No.: 3800003.00007 / 4905  
Supplemental Information Disclosure Statement

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

  
Stephanie Seidman  
Reg. No. 33,779

Attorney Docket No. 3800003.00007 / 4905  
**Address all correspondence to: 77202**  
Stephanie Seidman  
K&L Gates LLP  
3580 Carmel Mountain Road, Suite 200  
San Diego, California 92130  
Telephone: (858) 509-7410  
Facsimile: (858) 509-7460  
email: stephanie.seidman@klgates.com



04-01-10

Attorney Docket No.: 3800003.00007 / 4905

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nguyen *et al.*  
Serial No. : 10/677,977  
Filed : October 2, 2003  
Cust. No. : 77202  
Title : METHODS OF GENERATING AND SCREENING FOR PROTEASES  
WITH ALTERED SPECIFICITY

Art Unit : 1639  
Examiner : Teresa D. Wessendorf  
Conf. No. : 9061

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§1.97-1.98**

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 02-1818.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98.

The documents cited on the Forms PTO-1449 are in the English language, with the exception of the item noted below. Item AI (JP-A-5-503211) is in the Japanese language and an English language equivalent is listed (WO 91/05048, Item AJ). Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, this Supplemental Information Disclosure Statement (sIDS) includes a table listing an Examination Report, Office Action and Written Opinion cited in corresponding International Patent Applications:

1) Examination Report, issued October 21, 2009, in connection with Canadian Patent Application Serial No. 2,501,295 (Attorney Docket No. 3800003.00010/ 4905CA).

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
"Express Mail" Mailing Label Number EM 315456418 US  
Date of Deposit March 31, 2010.  
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Jon Levy

04/03/2010 10:00:00 AM 10/677,977  
10/677,977

2) Written Opinion, issued November 9, 2009, in connection with Singapore Patent Application Serial No. 200704897-8 (Attorney Docket No. 3800003.00022/ 4905BSG).

3) Office Action, issued February 5, 2010, in connection with Korean Patent Application Serial No. 10-2005-7005800 (Attorney Docket No. 3800003.00018/ 4905KR).

This Supplemental Information Disclosure Statement (sIDS) includes the application number of the application in which the IDS is being submitted, a column that provides a blank space next to each citation for the Examiner's initials, a heading on the listing that clearly indicates the list is an Information Disclosure Statement, and copies of Documents 1-3. Therefore, this sIDS is in compliance with 37 CFR §§ 1.97, 1.98 and MPEP § 609 and Applicant respectfully requests that Examiner consider and initial all information listed in the table below.

Examiner Initial	Document No.	Document
	1	Examination Report, issued October 21, 2009, in connection with Canadian Patent Application Serial No. 2,501,295.
	2	Written Opinion, issued November 9, 2009, in connection with Singapore Patent Application Serial No. 200704897-8.
	3	Office Action, issued February 25, 2010, in connection with Korean Patent Application Serial No. 10-2005-7005800.

In the Office Action dated January 20, 2010, the Examiner alleges that the Information Disclosure Statement filed on October 1, 2009, fails to comply with provisions 37 C.F.R. §§ 1.97, 1.98 and MPEP § 609 because "the list of other information i.e., copy of examination report from Australia and New Zealand submitted for consideration is not listed in a section separately from citations of other documents." Applicant respectfully disagrees. The Supplemental Information Disclosure Statement (sIDS) filed on October 1, 2009, included a table (i.e., a separate section) listing the Australian and New Zealand Examination Reports. In compliance with 37 CFR § 1.98 (a)(1), (a)(2) and (a)(3), the sIDS also included the application number of the application in which the sIDS was being submitted, a column that provided a blank space next to each citation for the Examiner's initials, a heading on the listing that clearly indicated the list is an Information Disclosure Statement, and copies of Documents 1 and 2. Therefore, the sIDS filed on October 1, 2009, is in compliance with 37 CFR §§ 1.97, 1.98 and MPEP § 609, and Applicant respectfully requests that Examiner consider and initial all information listed in the table.

The Examiner is requested to please review the file history of this application in PAIR. When submitting Information Disclosure Statements, the undersigned includes a transmittal letter, a paper providing information (IDS letter), and a Form PTO-1449. In some

Applicant : Nguyen et al.  
Serial No. : 10/677,977  
Filed : October 2, 2003

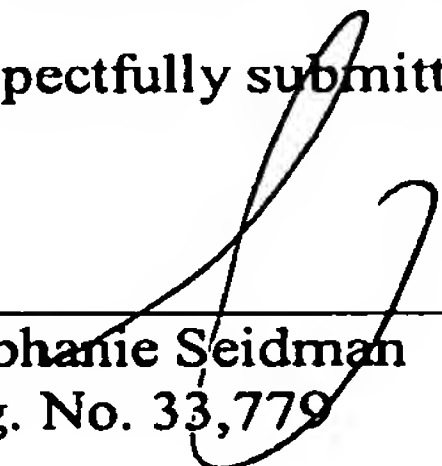
Attorney Docket No.: 3800003.00007 / 4905  
Supplemental Information Disclosure Statement

instances, the IDS letter includes a table with documents that require initials by the Examiner. It has come to the attention of the undersigned that Information Disclosure Statements have been misclassified in PAIR. Also the documents have been separated such that, at best, only parts of the documents are getting to the Examiner for review. In the Supplemental Information Disclosure Statements filed on September 12, 2008; June 11, 2009; July 10, 2009; and October 1, 2009, the transmittal letter and accompanying IDS letter providing information have been classified together as a transmittal letter (TRAN.LET). To address this, the undersigned has contacted the Examiner and requested that documents submitted in the Information Disclosure Statement tables be considered and initialed by the Examiner.

Although these documents and applications are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

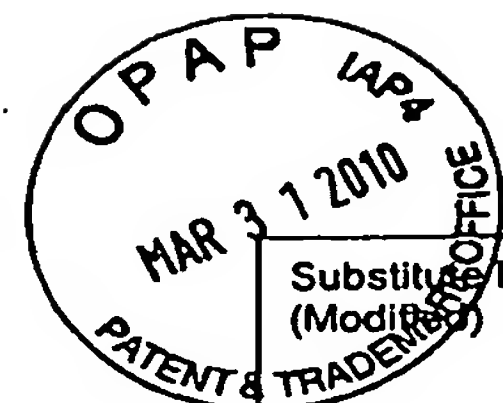
Respectfully submitted,



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Stephanie Seidman  
Reg. No. 33,779

Attorney Docket No. 3800003.00007 / 4905  
**Address all correspondence to: 77202**  
Stephanie Seidman  
K&L Gates LLP  
3580 Carmel Mountain Road, Suite 200  
San Diego, California 92130  
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Facsimile: (858) 509-7460  
email: stephanie.seidman@klgates.com



Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 3800003.00007/4905	Application No. 10/677,977
<b>List of Patents and Publications for Applicant's Information Disclosure Statement</b>  (37 CFR §1.98(b))		Applicant Nguyen <i>et al.</i>	
		Filing Date October 2, 2003	Group Art Unit 1639

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	2003/0050251	03/13/03	Semple et al.	514	19	03/05/02
	AB	2005/0130883	06/16/05	Roller et al.	514	10	09/30/04
	AC	2005/0158297	07/21/05	Jensenius	424	94.6	01/11/05
	AD	2009/0155248	06/18/09	Craik et al.	424	133.1	01/14/08
	AE	2009/0175873	07/09/09	Liu	424	139.1	05/29/08
	AF	2009/0208474	08/20/09	Haupts	424	94.3	12/21/07
	AG	2009/0208440	08/20/09	Haupts	424	70.14	01/04/08
	AH	7,439,226	10/21/08	Roller et al.	514	10	09/30/04

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AI	JP-A-5-503211	06/03/93	JP				X* (Item AJ)
	AJ	WO 91/05048	04/18/91	WIPO				
	AK	WO 00/53232	09/14/00	WIPO				
	AL	WO 01/97794	12/27/01	WIPO				
	AM	WO 02/08392	01/31/02	WIPO				
	AN	WO 09/126307	10/15/09	WIPO				

X\* = An English language equivalent is provided.

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AO	Bode et al., "The refined 1.0-Å X-ray crystal structure of D-Phe-Pro-Arg chloromethylketone-inhibited human $\alpha$ -thrombin: Structure analysis, overall structure, electrostatic properties, detailed active-site geometry, and structure-function relationships," <i>Protein Science</i> 1:426-471 (1992).
	AP	Encell and Loeb, "Redesigning the substrate specificity of human O(6)-alkylguanine-DNA alkyltransferase. Mutants with enhanced repair of O(4)-methylthymine," <i>Biochem.</i> 38:12097-12103 (1999).
	AQ	Greer, J., "Comparative modeling methods: Application to the family of mammalian serine proteases," <i>PROTEINS: Structure, Function and Genetics</i> 7:317-334 (1990).
	AR	Kuo et al., "Comparative evaluation of the antitumor activity of antiangiogenic proteins delivered by gene transfer," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 98(8):4605-4610 (2001).
	AS	Landis and Loeb, "Random sequence mutagenesis and resistance to 5-fluorouridine in human thymidylate synthases," <i>J. Biol. Chem.</i> 273:25809-25817 (1998).
	AT	MEROPS the Peptidase Database, retrieved from the Internet: <URL: merops.sanger.ac.uk/cgi-bin/name_index?id=P;action=G, [accessed on 03.24.10] [16 pages].

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

<b>Substitute Form PTO-1449</b> (Modified)  <b>List of Patents and Publications for Applicant's</b> <b>Information Disclosure Statement</b>  (37 CFR §1.98(b))	<b>U.S. Department of Commerce</b> <b>Patent and Trademark Office</b>		<b>Attorney's Docket No.</b> 3800003.00007/4905	<b>Application No.</b> 10/677,977
	<b>Applicant</b> Nguyen <i>et al.</i>			
	<b>Filing Date</b> October 2, 2003		<b>Group Art Unit</b> 1639	

<b>Other Documents (include Author, Title, Date, and Place of Publication)</b>		
<b>Examiner Initial</b>	<b>Desig. ID</b>	<b>Document</b>
	AU	Mignatti and Rifkin, "Biology and biochemistry of proteinases in tumor invasion," <i>Physiol. Rev.</i> 73:161-195 (1993).

<b>Examiner Signature</b>	<b>Date Considered</b>
<b>EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Nguyen *et al.*  
Serial No. : 10/677,977  
Filed : October 2, 2003

Art Unit : 1639  
Examiner : Teresa D. Wessendorf  
Conf. No. : 9061  
Cust. No. : 77202

Title : **METHODS OF GENERATING AND SCREENING FOR PROTEASES  
WITH ALTERED SPECIFICITY**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§1.97-1.98**

Dear Sir:

Because this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 02-1818.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98.

The documents cited on the Forms PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Although these documents and applications are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the documents, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

07/22/2010 HDESTA1 00000013 021818 10677977  
01 FC:1806 180.00 DA

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
"Express Mail" Mailing Label Number EM 315458250 US.  
Date of Deposit July 20, 2010.  
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

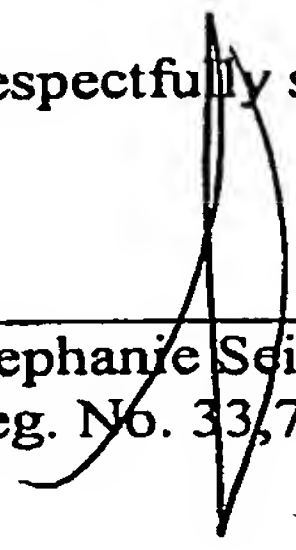
Jon Levy

Applicant : Nguyen et al.  
Serial No. : 10/677,977  
Filed : October 2, 2003

Attorney Docket No.: 3800003.00007 / 4905  
Supplemental Information Disclosure Statement

Applicant respectfully requests that the Examiner review the foregoing documents and they be made of record in the file history of the above-captioned application.

Respectfully submitted,



---

Stephanie Seidman  
Reg. No. 33,779

Attorney Docket No. 3800003.00007 / 4905  
**Address all correspondence to: 77202**  
Stephanie Seidman  
K&L Gates LLP  
3580 Carmel Mountain Road, Suite 200  
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email: stephanie.seidman@klgates.com

Substitute Form PTO-1449 (Modified)  <b>U.S. Department of Commerce Patent and Trademark Office</b>  <b>List of Patents and Publications for Applicant's Information Disclosure Statement</b>  (37 CFR §1.98(b))	Attorney's Docket No. <b>3800003.00007/4905</b>	Application No. <b>10/677,977</b>
	Applicant <b>Nguyen <i>et al.</i></b>	
	Filing Date <b>October 2, 2003</b>	Group Art Unit <b>1639</b>

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
None							

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AA	1 504 117	07/18/07	EP				

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
None		

Examiner Signature	Date Considered
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	